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United States Department of Energy
Office of Hearings and Appeals

In the Matter of:		
Siemens Medical Solutions USA Inc.	)	
Siemens Healthcare Diagnostics Inc.	)	Case No.: EXS-16-0012
	)	
Filing Date: May 31, 2016	)	
	)	

Issued: July 5, 2016

Decision and Order on Application for Stay

On May 31, 2016,[1] Siemens Medical Solutions USA Inc. and Siemens Healthcare Diagnostics Inc. (Siemens) filed an Application for Stay of the applicable provisions of the Energy Conservation Program: Energy Conservation Standards for Commercial and Industrial Electric Motors (Electric Motor Efficiency Standards or Final Rule), published on May 29, 2014, 79 Fed. Reg. 30934, and codified at 10 C.F.R. Part 431. Siemens requests that it be granted a stay from compliance with the Final Rule until the DOE's Office of Hearings and Appeals (OHA) can decide the merits of its Application for Exception from the Final Rule, OHA Case No. EXC-16-0012, which it filed concurrently with its Applications for Stay. For the reasons discussed below, we will grant the Application for Stay.

I. Background

Title III of the Energy Policy and Conservation Act of 1975, Public Law 94-163 (42 U.S.C. 6291 *et seq.*) (EPCA) initiated a variety of measures designed to improve energy efficiency of certain

[1] Upon receiving Siemens' Applications, we advised Siemens that, before we could proceed with our evaluation of its requests, the firm must: (1) correct a procedural deficiency relating to service upon "potentially aggrieved parties," 10 CFR § 1003.23(a), and (2) clarify whether the firm was eligible to receive exception relief as an importer (and thus "a manufacturer", see 42 U.S.C. § 6291(10)) of electric motors. June 3, 2016, Letter from Fred L. Brown, Deputy Director, OHA, to Hans Beinke, Siemens. Siemens corrected the procedural deficiency and provided the requested clarifying information in supplemental submissions dated June 9, June 17 and June 22, 2016.

products. The Energy Policy Act of 1992, Pub. L. 102-486, amended EPCA to establish energy efficiency standards for some types of commercial and industrial equipment, including certain electric motors. The energy efficiency standards for electric motors, written directly into the Act, came into effect five years later, on October 24, 1997. Pub. L. 1-486, Sec. 122(b).

In 2007, Congress enacted the Energy Independence and Security Act of 2007 (EISA), Public Law 110-140, which amended the EPCA by updating the energy conservation standards for those electric motors already covered by the EPCA and established energy conservation standards for a larger scope of electric motors not already covered by standards. See 42 U.S.C. § 6313(b)(2) (codifying specific standards prescribed by Section 313(b) of EISA for general purpose electric motors (Subtypes I and II), fire pump motors, and NEMA Design B general purpose electric motors). Additionally, Congress further amended the EPCA by providing DOE with the explicit authority to establish regulatory coverage over "other motors" that fall outside of one of these prescribed motor types. See American Energy Manufacturing Technical Corrections Act, Pub. L. 112-210 (December 18, 2012). Consistent with these legislative provisions, the DOE issued the Electric Motor Efficiency Standards in which it raised the efficiency standards for some electric motors, but more significantly, applied "the standards currently in place to a wider scope of motors that DOE does not [currently] regulate." 79 Fed. Reg. 30934 (May 29, 2014). Particularly relevant to the present proceeding, the Final Rule extended energy efficiency standards to certain general purpose motors that were previously not subject to regulation. *See* 10 C.F.R. § 431.25. Compliance with the Electric Motor Efficiency Standards is required as of June 1, 2016.

As explained in its underlying Application for Exception, Siemens is a leading manufacturer and service provider for medical imaging and in-vitro diagnostic products (e.g. magnetic resonance imaging (MRI) machines and computed tomography (CT) equipment). In order to operate, in many instances these products utilize general purpose motors that were previously not covered by DOE efficiency standards but have now been made subject to regulation under the Final Rule. Siemens not only sells new medical equipment to its customers, which are primarily healthcare institutions, but also services previously sold equipment which involves replacing an electric motor as part of its repair. Siemens asserts that the firm requires additional time to assess the impact of the Electric Motor Efficiency Standards upon its business and to determine its path toward compliance.[2] Pending adjudication of its Application for Exception, Siemens requests relief from the Final Rule with respect to electric motors installed in new medical imaging and in-vitro diagnostic medical devices produced by the firm, as well as for replacement electric motors that Siemens installs in repairing existing medical devices. Siemens contends that the firm, its customers and patients of its customers will suffer a serious hardship and gross inequity in the absence of stay relief.

[2] In its Application for Exception, Siemens requests that the firm be granted thirty days to supplement its Application with more precise information about its regulatory logistical challenges and a timeline for compliance with the Final Rule. On June 30, 2016, Siemens filed its Supplement to Application for Exception (Application Supplement) which describes Siemens' intended path forward toward compliance.

In further support of its exception and stay requests, Siemens submits that "the number of covered electric motors embraced by our application is not large." Siemens Application for Exception at 3. While Siemens cannot precisely project the number of new and replacement motors the firm's customers will require during the pendency of its Application for Exception, Siemens has attached to its Application a listing to the type and number of electric motors that it supplied in either new diagnostic devices or as replacement motors during 2015. Siemens Application, Appendix A. Based upon revised data subsequently submitted by Siemens, Siemens sold (in new equipment or replaced in existing equipment) a total of XXX motors[3] of varying types that will now be subject to regulation under the Final Rule. *See* Application Supplement, Appendix A (Amended). Additional information provided by Siemens (see note 1, *supra*), however, has clarified that Siemens is not the "manufacturer" and thus has no standing to request exception or stay relief with respect to the great majority of these motors.

In our letter acknowledging receipt of Siemens' Applications, we explained OHA has authority to issue exception relief only to those entities being regulated, in this instance the manufacturers of electric motors produced for sale in U.S. commerce. OHA may grant exception relief to the extent a manufacturer is able to show that it will suffer a gross inequity, serious hardship or unfair distribution of burdens as a result of meeting the revised DOE efficiency standard. *See* 10 C.F.R. Part 1003, Subpart B; Department of Energy Organization Act, 42 U.S.C. § 7194. The Energy Policy and Conservation Act of 1975 (EPCA), 42 U.S.C. §§ 6291 *et seq*., pursuant to which the Electric Motor Efficiency Standards were promulgated, defines "manufacturer" as "any person who manufactures industrial equipment" and defines "manufacture" as to "manufacture, produce, assemble, or import." *See* 42 U.S.C. § 6311 (5); 42 U.S.C. § 6291 (10). We therefore requested that Siemens provide additional information clarifying whether the electric motors supplied by Siemens, contained in new equipment or as replacement motors, are: 1) produced domestically, 2) produced overseas and Siemens is the importer of record, and 3) produced overseas but Siemens is not the importer of record. June 3, 2016, Letter from Fred L. Brown, Deputy Director, OHA, to Hans Beinke, Siemens.

On June 22, 2016, Siemens submitted supplemental information in response to our June 3, 2016, letter stating: "Siemens is the official importer of record and can provide verifying U.S. Customs documentation for the XXXXX XXXXXX XXXXXXX XXXXXX XXXXX devices and replacement motors. The XXXXXX XXXXXX XXX devices are not imported. The motors are imported but we are not the official importer of record." June 22, 2016, Email from Hans Beinke, Siemens, to Fred L. Brown, Deputy Director, OHA. The revised Appendix attached to

[3] In its May 31, 2016, Application, Siemens approximated that, during the preceding year, the firm sold XX motors (in new equipment or as a replacement) that would be subject to regulation under the Final Rule. Subsequently, in its supplemental submission of June 17, 2016, Siemens reduced this number (XX) by XX to XX motors, stating that "[u]pon further investigation, we no longer need an exception to the motors contained in our cyclotron device." Finally, in its Application Supplement, Siemens further reduced the number of affected motors from XXX to XX, comprised of XX motors in CT (Computed Tomography) devices, XX motors in MR (Magnetic Resonance) devices, and XXX motors in IVD (In Vitro Diagnostic) devices.

Siemens' Application Supplement shows that MR and CT devices and replacement motors comprise only XX (XXX%) of the XXX electric motors sold by the firm in 2015 which are now subject to regulation. The remaining XXX motors are contained in XXXXX XXXXX XXX devices for which Siemens is not the importer of record. We emphasize that it is only with respect to the MR and CT electric motors that Siemens is the "manufacturer" (as the importer of record) and therefore has standing to request exception and stay relief. Thus, our consideration of Siemens' Application for Stay, set forth below, pertains only to the MR and CT electric motors sold by Siemens.

II. Application for Stay

In its Application for Stay, Siemens request stay of enforcement of the electric motor energy efficiency standards of the Final Rule while its Application for Exception is under review. The criteria to be considered by the OHA in determining whether a stay should be granted are:

> (1) Whether a showing has been made that an irreparable injury will result in the event that the stay is denied;
> (2) Whether a showing has been made that a denial of the stay will result in a more immediate hardship or inequity to the applicant than a grant of the stay would cause to other persons affected by the proceeding;
> (3) Whether a showing has been made that it would be desirable for public policy reasons to grant immediate relief pending a decision by OHA on the merits;
> (4) Whether a showing has been made that it is impossible for the applicant to fulfill the requirements of an outstanding order or regulatory provision; and
> (5) Whether a showing has been made that there is a strong likelihood of success on the merits.

10 C.F.R. § 1003.45(b). These criteria are discussed below, *seriatim.* As set forth below, we have determined that Siemens' stay request should be approved.

(1) Irreparable Injury

Based upon our review, we are satisfied that Siemens has made a plausible showing of irreparable injury. Siemens states in its stay application that not only the firm but its customers, healthcare providers and patients, will suffer irreparable injury in the absence of stay relief. In this regard, Siemens states that medical imaging devices are heavily regulated by the U.S. Food & Drug Administration (FDA) which requires design verification and performance validation for all components, including electric motors, comprising these devices. S*ee* Siemens' Application for Exception at 2-3. Siemens asserts that "[t]o introduce new electric motors into our already FDA approved medical devices that would meet energy conservation standards under the amended DOE rule for electric motors will require extensive new testing and evaluation to

ensure safety and efficacy of our equipment." Siemens Application for Stay at 2. Siemens contends that the firm and its customers will face irreparable injury if Siemens cannot meet its contractual commitments to deliver FDA-approved designs of equipment that is currently on order or to promptly repair existing equipment. *Id.*

(2) Immediate Hardship or Inequity

We are also persuaded that denial of the stay will result in a more immediate hardship to Siemens than a grant of the stay would cause to other affected persons. In this regard, Siemens cites the injury to the firm and its existing customers, described above. Siemens states that "we can reasonably foresee that in the very near future in some cases . . . we will have to secure a replacement electric motor, particularly in connection with a repair of the medical device that was either not manufactured or imported prior to June 1, 2016." *Id.*

(3) Public Policy

We have also determined that public policy weighs in favor of granting Siemens request for a stay. Siemens asserts that the approval of stay relief is supported by vital public policy interests of meeting the public health requirements of healthcare providers and their patients, as well as FDA regulatory requirements that medical devices be safe and effective.

(4) Possibility of Compliance

Siemens asserts that, in the absence of stay relief, it will be impossible for the firm to provide new medical devices housing compliant electric motors, or to replace all damaged or impaired electric motors in medical equipment in a timely way, because of the extensive testing, verification and validation of the use of compliant electric motors required by FDA regulations. In its Application Supplement, Siemens states that three steps will be required to come into compliance with the new Electric Motor Efficiency Standards: first, its electric motor suppliers must redesign their motors and subassemblies, and second and third, Siemens must perform design verification and performance validation in accordance with FDA standards. *See* Application Supplement at 1. According to Siemens, the first step could take from two to nine months, while the FDA process will take approximately three months. *Id.*

(5) Likelihood of Success on the Merits

It is clear from our preliminary analysis of Siemens' exception request that additional information and supporting evidence will be necessary in order to determine the scope of any exception relief to which Siemens may be entitled. However, based upon the circumstances presented, we are satisfied that there is a sufficient likelihood of success on the merits of Siemens' Application for Exception to warrant the approval of the requested stay.

It Is Therefore Ordered That:

(1) The Application for Stay filed by Siemens Medical Solutions USA Inc. and Siemens Healthcare Diagnostics Inc. (Siemens), on May 31, 2016, is hereby granted as set forth in paragraph (2) below.

(2) The June 1, 2016, compliance date of the Energy Conservation Program: Energy Conservation Standards for Commercial and Industrial Electric Motors, published on May 29, 2014, 79 Fed. Reg. 30934, and codified at 10 C.F.R. Part 431, is hereby stayed with respect to electric motors contained in new MR (Magnetic Resonance) and CT (Computed Tomography) devices sold by Siemens, or supplied by Siemens as replacement motors in such devices, for which Siemens is the official importer of record, until the Office of Hearings and Appeals reaches a decision on the Application for Exception filed by Siemens on May 31, 2016, OHA Case No. EXC-16-0012.

Poli A. Marmolejos
Director
Office of Hearings and Appeals

Date: July 5, 2016